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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,114	11/22/2000	Hirohiko Hirochika	MAFF-1	2997

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EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/721,114	HIROCHIKA ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-11* is/are pending in the application.

4a) Of the above claim(s) *4-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/02 has been entered.

2. This action is written in response applicant's correspondence submitted 12/12/02, paper number 14. Claim 1 has been amended. Claims 2-3 were cancelled. Claims 4-11 were added and are subject to restriction as set forth below. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to an isolated polynucleotide, classified in class 536, subclass 23.1.

II. Claims 4, 6, 8, and 10, drawn to genetically engineered plants and plant cells having enhanced expression of a polypeptide, classified in class 410, subclass 419 and class 800, subclass 295.

III. Claims 5, 7, 9, and 11, drawn to genetically engineered plants and plant cells having reduced expression of a polypeptide, classified in class 410, subclass 419 and class 800, subclass 295.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The transgenic plants and cells of Group II-III are compositions made up of structurally and functionally complex biological systems. The transgenic plants and cells of groups II and III are distinct from one another because one has reduced expression of a polypeptide while the other has enhanced expression. The differences in expression presumably will result in different functions and properties for the transgenic organisms. Furthermore, the products of Groups I, II, and III can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays or to express the encoded polypeptides, while transgenic plants and cells can be used in assays to study the effects of the transgenic polypeptide or can be used for some characteristic imparted upon them by the presence of the transgene. The transgenic cells can be used to regenerate the transgenic plants. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and III are patentably distinct from each other.

4. Newly submitted claims 4-11 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons set forth herein.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 4-11 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 101

5. Claim1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

Claim 1 is drawn to a polynucleotide encoding polypeptide involved in a signal transduction system for brassinosteroid hormone, said polypeptide consisting of the amino acid sequence from Met at position 1 to Arg at position 1057 of SEQ ID NO: 2. The specification asserts that these polynucleotides are of use in plant breeding (p. 14). Specifically, the specification teaches that "by introducing the present polynucleotide into plants and artificially controlling various effects in which the brassinosteroid hormone is involved, it is expected that effects such as growth promotion, yield increase, quality improvement, maturation enhancement, and tolerance against biotic and abiotic stresses can be controlled... (p. 14)." However, beyond this assertion, the specification does not provide any guidance or evidence that such effects can be achieved in plants.

The specification demonstrates in two different strains of rice that the disruption of the expression of instant SEQ ID NO: 2 causes dwarfism in plants (see examples 2 and 3). The specification further demonstrates that in wild type plants SEQ ID NO: 2 is expressed in a variety of different plant tissues (see example 4). The specification further teaches that there are

putative nuclear localization signals and ATP/GTP binding domains in the polypeptide encoded by instant SEQ ID NO: 2 (see example 5). Finally, the specification demonstrates that while normal plant leaves bend in response to treatment with brassinolide, the mutant plants with disrupted SEQ ID NO: 2 do not respond to the treatment (see example 6). Thus, it is reasonable to conclude that the polypeptide encoded by instant SEQ ID NO: 2 has some functionality in the response of rice plants to brassinolide. Nonetheless, the determination that a polypeptide is part of a particular pathway does not equate to the provision of a specific, substantial and credible utility.

Altmann provides a review of advances in brassinosteroid molecular genetics (Current Opinion in Plant Biology, 1998, Vol. 1, pages 378-783). Altmann teaches that mutant plants that are insensitive to brassinosteroids may be blocked in the primary perception of the BR signal, in essential components of the signal transduction pathway, or in the target genes that are responsible for the major components of the response (p. 781, second column). Thus, the instant polypeptides "involvement" in the signaling transduction for brassinosteriod hormone may be at any number of positions in a complicated pathway. Functionality in any one of these capacities would have an effect on how and when the instant polynucleotides would be useful.

In order to utilized the instant invention, further experimentation would be necessary to reasonably confirm the activity of the claimed polynucleotides and how they can be used to effect the goals postulated by applicant. In genetically modified plants, the introduced transgenes are sometimes not expressed, and they can also result in co-suppression effects. None of these effects are predictable, and the mechanisms of gene silencing are still not fully understood. Thus, success in modification of gene expression or of phenotypic characteristics in

plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. Moreover, the phenotypic characteristics that will result from expression of a given DNA construct cannot be reliably predicted. In fact, often the expected phenotypic result is not achieved. Thus, in light of the instant disclosure, the proposed utility is not considered to be substantial because further experimentation would be necessary to reasonably confirm a use for the claimed polynucleotides.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Response to Remarks

In response to the 101 utility rejection and the 112 1st paragraph lack of enablement rejection, applicant traverses the examiner's assertion that the specification does not provide evidence of a causative relationship between the presence of the mutated form of the claimed polynucleotide and an altered response to brassinosteroid hormone. This concern raised by the examiner is withdrawn in view of a careful review of the examples and arguments, and applicant's amendment to the claim. As noted in the revised rejection, it is reasonable to conclude based on the evidence of record that the polypeptide encoded by instant SEQ ID NO: 2 has some functionality in the response of rice plants to brassinolide. However, this is not sufficient to provide a substantial or specific utility for the claimed invention.

Applicant sets forth in the remarks filed 12/12/02 on page 6 that the instant invention provides a useful research tool for understanding the molecular genetics of brassinosteroid biosynthesis and mode of action. First, it is noted that this utility is not asserted in the specification. Nonetheless, this utility is not a specific utility because it belongs to a general class of invention. Essentially this asserted utility is that the polypeptide encoded by SEQ ID NO: 2 could be used to study itself and its involvement in a biochemical pathway. Any polynucleotide encoding a polypeptide has that particular utility. This utility is an invitation to do further research to determine the functionality of instant SEQ ID NO: 2, and thus it is not a substantial utility either. This utility constitutes an invitation for one to undertake further experimentation to reasonably confirm that what effects could be achieved by using the instant polynucleotides. With regard to the rejection under 112 1st paragraph, the issue herein is not how to make the claimed polynucleotide, but instead how to use the claimed polynucleotide, as

is discussed in the rejection and arguments herein. For these reasons, the rejections are maintained.

The rejection under 112 1st paragraph for lack of written description is withdrawn in light of applicant's amendments to the claims. Likewise the rejection under 112 2nd paragraph is obviated in view of the claim amendments.

The art rejections under both the EMBL and GenBank disclosures by Sasaki *et al.* are hereby withdrawn in light of Applicant's amendments to the claims. Sasaki *et al.* do not teach or suggest a polynucleotide that encodes a polypeptide **consisting of** the amino acid sequence from Met at position 1 to Arg at position 1057 of instant SEQ ID NO: 2. Furthermore, the rejection in view of the GenBank Sasaki *et al.* reference is also overcome by applicant's provision of the translated foreign priority document. The declaration filed under 1.131 is not discussed herein because it is moot in light of applicant's amendment to the claims and the subsequent withdrawal of the rejection.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C Einsmann
Examiner
Art Unit 1634

February 13, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER